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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/414,384	10/07/1999	ANDREW CLARK	0037.00	3236

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No.

09/414,384

Applicant(s)

ANDREW CLARK ET AL.

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 2, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 05/06/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/414,384 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (EP 0 808 635 A2).

As to claim 21, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator that provides a high flow resistance and subsequently provides a lower flow resistance.

While Howlett is silent as to a particular quantity of flow resistance being provided, Howlett (col.3, lines 43-50) discloses that the particular flow resistance provided by the device can be controlled by selection of a diaphragm having a particular flexibility in combination with dimensions

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of air inlet (31) and gap (36). Consequently, the particular quantity of flow resistance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance.

As to claims 22-25, Howlett, as discussed above with respect to the particular quantity of flow resistance the particular quantity of flow rate can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance and/or flow rate.

As to claims 26 and 27, the particular period of time during which the flow resistance is applied by the device of Howlett will vary with the manner of use of the device. That is, the duration of time during which flow resistance is applied is directly proportional to the duration of a particular patient's inhalation period. Consequently, this time period can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular time period.

As to claims 28 and 29, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator that provides a high flow resistance and subsequently provides a lower flow resistance.

While Howlett is silent as to a particular quantity of flow resistance being provided, Howlett (col.3, lines 43-50) discloses that the particular flow resistance provided by the device can be controlled by selection of a diaphragm having a particular flexibility in combination with dimensions

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of air inlet (31) and gap (36). Consequently, the particular quantity of flow resistance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance. As to the claimed flow rate, the particular quantity of flow resistance and therefore the particular quantity of flow rate can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance and/or flow rate.

Claims 30 and 31 are substantially equivalent in scope to claims 22 and 26 respectively, and are included in Howlett for the reasons discussed above with respect to claims 22 and 26.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 32 and 36 are rejected under 35 U.S.C. 102(a) as being anticipated by Howlett (EP 0 808 635 A2).

As to claim 32, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator to provide a first flow rate and subsequently provides a second flow resistance to provide a second flow rate.

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As to the amendment, "...the second flow resistance being less than the first flow resistance.", the arrangements of figs.2-4 of Howlett show a flow resistance modulator which acts to restricts a patient's inhaled flow when it (inhaled flow) exceeds a predetermined threshold thereby providing a high flow resistance and subsequently relaxes if and when such a patient's inhaled flow rate decreases to a level which is beneath the predetermined threshold for restricting the flow thereby subsequently providing a lower flow resistance.

As to claim 36, during the exertion of the first and second flow resistances by the flow resistance modulator of Howlett causes the inhaled air flowing therethrough to do so at first and second flow rates.

6. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (EP 0 808 635 A2).

Claims 33-35 are substantially equivalent in scope to claims 26,24,25 respectively, and are included in Howlett for the reasons set forth above with respect to claims 26,24 and 25.

Response to Arguments

7. Applicant's arguments filed 09/28/2001 have been fully considered but they are not persuasive.

Applicant's assertion that Howlett lacks a flow resistance modulator which provides a high flow resistance is disagreed with because the enlarged illustrations of figs.2-4 each show a flow

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resistance modulator which is intended to control the flow rate of air through the inhaler during patient inhalation. If a patient inhales too forcibly, the flow resistance modulator (figs.2-4) begins to close off some or all of the air inlets to the inhaler in dependence upon the degree of forcefulness of such an inhalation and in dependence upon the physical design parameters of the flow resistance modulator. This relates to the claims of the instant application as follows: the arrangements of figs.2-4 of Howlett show a flow resistance modulator which acts to restricts a patient's inhaled flow when it (inhaled flow) exceeds a predetermined threshold thereby providing a high flow resistance and subsequently relaxes if and when such a patient's inhaled flow rate decreases to a level which is beneath the predetermined threshold for restricting the flow thereby subsequently providing a lower flow resistance.

Applicant's arguments regarding an alleged lack of motivation for altering the flow resistance modulator (figs.2-4) of Howlett to achieve particular desired flow resistance/rates is disagreed with because of the disclosure by Howlett (col.3, lines 46-50) which addresses how (e.g. by adjustment of diaphragm flexibility) one of ordinary skill might make a device which would achieve control of inhaled flow rates of 30-60 liters per minute. Therefore, it would have been obvious to modify the diaphragm flexibility to achieve the particular inhaled flow rate(s) desired by a given patient. Such an adjustment would have been necessary in the case in which a child is using the device rather than an adult or when a patient of less than average breath capacity is using the device or even when a patient subject to asthma attacks is using the device.

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8. Applicant's arguments filed 03/12/2002 have been fully considered but they are not persuasive.

Applicant's argument that Howlett does not qualify as prior art under 35 USC 102(b) is persuasive; however, Howlett does qualify as prior art under 35 USC 102 (a).

Applicant's argument that Howlett does not anticipate claim 32 is disagreed with. The initial and subsequent resistances to flow exerted by the flow resistance modulator of Howlett may follow a sequence of minimum resistance followed by a resistance increase; however, this sequence only occurs if a patient's initial inhalation (negative) pressure is initially below the threshold of the flow resistance modulator AND any subsequent inhalation (negative) pressure exceeds that of the initial inhalation pressure. On the other hand, if such a patient's initial inhalation (negative) pressure exceeds the threshold of the flow resistance modulator AND any subsequent inhalation (negative) pressure is both below the threshold of the flow resistance modulator and below the initial inhalation pressure, then it is reasonable to conclude that the second flow resistance exerted by the flow resistance modulator is less than the first flow resistance, as recited in the amendment to claim 32.

Applicant's arguments regarding claim 21 are disagreed with. The Howlett device discloses structure (flow resistance modulator) which is fully capable of providing the recited function of exerting resistances to flow of at least $0.4 \text{ (cm H}_2\text{O)}^{1/2}/\text{SLM}$. That is, the language of claim 21 defines a flow resistance modulator that provides a flow rate of at least $0.4 \text{ (cm H}_2\text{O)}^{1/2}/\text{SLM}$ but does not provide structural elements which would cause the claimed flow resistance

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modulator to provide the recited flow resistance and thereby distinguish structurally from the flow resistance modulator of Howlett.

Applicant's arguments regarding the pressure necessary to generate $0.4 \text{ (cm H}_2\text{O)}^{1/2}/\text{SLM}$ is noted; however, it is submitted that the text of Howlett (col.3, lines 43-50) is illustrative of the recognition that one of ordinary skill would look to modify any of a combination of diaphragm flexibility, diameter of inlet #31 and the size of air gap #36. Consequently, while Howlett discloses 30 to 60 liters/min. flow rate, one of ordinary skill would realize that any of a combination of the abovementioned factors may be employed to provide a desired flow rate.

As to applicant's arguments regarding "mere routine obvious experimentation and observation" in modifying the flow rate of the flow resistance modulator of Howlett, the motivation for such a modification would come from the intended use of the device. For example, if one wished to use the device on asthmatics, or children, or elderly patients then due to a lack of ability to generate strong inhalation pressure, one of ordinary skill would be motivated to modify those elements (i.e. diaphragm flexibility, diameter of inlet #31 and the size of air gap #36) which would enable patient's with weakened abilities to generate inhalation pressures to effectively use the device.

Applicant's contention that Howlett disclosure provides no mention of device being designed solely for healthy patients may be accurate; however, such is not seen as fatal to the position taken by the examiner regarding the reasons for modifying the flow rate and pressure exerted by the flow resistance modulator. The groups of patients mentioned above may have healthy respiratory

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systems but make use of the device of Howlett for treating a systemic disease such as diabetes.

One of ordinary skill would still wish to tailor the device to accommodate the individual abilities of these patients to generate sufficient inhalation pressures to effectively use the device.

9. Applicant's arguments filed 12/02/2002 have been fully considered but they are not persuasive.

Applicant's arguments regarding claim 32 are not persuasive because while Howlett may not expressly disclose the claimed sequence of providing a first and second flow resistance, the second being less than the first, Howlett does disclose structure which inherently can perform the recited functions of providing a first and second flow resistance, the second being less than the first. Accordingly, Howlett does anticipate claim 32 for the reasons given above in the body of the rejection.

Applicant's arguments regarding claims 21-31, specifically with respect to the flow rate and pressure analysis are noted but not persuasive. While applicant's conclusion that an uncomfortably large negative pressure would be necessary to achieve a flow rate of 30-60 liters per minute in Howlett may be accurate, the analysis does not take into account the express disclosure of Howlett (col.3, lines 43-50) which teaches the variation of diaphragm flexibility, diameter of air inlet (31) and the size of gap (36) as a way of controlling flow rate to 30-60 liters per minute. This lack of consideration of the parameters expressly disclosed by the prior art as being employed to achieve a given flow rate renders applicant's arguments in this regard incomplete and therefore, not persuasive.

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Conclusion

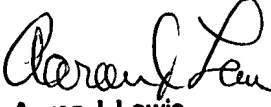
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

February 10, 2003


Aaron J. Lewis
Primary Examiner